

REMARKS/ARGUMENTS

Claims 7-20 and 23-30 are currently pending. Claims 1-6 and 21-22 have been cancelled. Claims 7 and 17 have been amended. Claims 24-30 have been added. No new matter has been added with the amendment. Reconsideration of this Application and entry of this Amendment is requested. In view of the amendments and following remarks, favorable consideration and allowance of the application is respectfully requested.

35 U.S.C. §112 Rejections

Claims 21 and 22 were rejected under 35 U.S.C. 112, first paragraph as failing to comply with the written description requirement. This rejection is traversed. The Examiner alleges that the specification lacks disclosure of the stent having “an uncoated end.” The Examiner misquotes both claim 21 and 22. Both claim 21 and claim 22 recites “wherein the stent further comprises an uncoated cut end.” The specification provides disclosure for this limitation at page 7 lines 20-27. Specifically, the Applicant discloses that after the stent is coated, the detachable portions are removed by cutting and the cut ends of the remaining stent are smoothed and polished. Those with skill in the art would readily recognize that smoothing and polishing the cut ends of a coated stent would necessarily leave a stent with “an uncoated cut end” as recited in claims 21 and 22. For this reason, the withdrawal of the rejection of claims 21 and 22 is requested.

35 U.S.C. §102 Rejections

A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference. *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). The identical invention must be shown in as complete detail as is contained in the . . . claim. *Richardson v. Suzuki Motor Co.*, 868 F.2d 1226, 1236, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989).

- A. Claims 1-6, 17, 19-20 and 23 were rejected under 35 U.S.C. 102(b) as being anticipated by Buirge (US5735897).

The Examiner's rejection of claims 1-6, 17, 19-20 and 23 under 35 U.S.C. 102(b) as being anticipated by the Buirge patent is traversed. As noted above, claims 1-6 have been cancelled by the above amendment, thereby obviating the rejection.

To warrant the §102(b) rejection of remaining claims 17, 19-20 and 23, the Buirge patent must show each and every limitation of independent claims 17 and 23 in as complete detail as

contained in the independent claims. The Applicant has thoroughly considered the Non-Final Office Action mailed September 22, 2006, and respectfully notes that the Buirge patent fails to meet this requirement.

Claim 17 recites a system for producing a stent including means for providing a preliminary stent comprising a permanent portion and a detachable portion; means for retaining the preliminary stent by an end of the detachable portion; means for applying a coating to an outer surface of the preliminary stent; and means for detaching the detachable portion with a pooled coating from the permanent portion. The Buirge patent does not teach all of these claim elements. Claim 17, and those depending from claim 17, invoke 35 U.S.C. 112, sixth paragraph. As such the Examiner must apply 35 U.S.C. 112, sixth paragraph and give these claims their broadest reasonable interpretation, in light of and consistent with the written description of the invention in the application. See MPEP 2181. Given this stricture, Buirge cannot anticipate claim 17.

First, Buirge does not teach means for providing a preliminary stent 150 comprising a permanent portion 158 and a detachable portion 154 (see FIG. 2). At most, Buirge teaches a method of forming a long tube of a stent-pump that is then cut into individual stents that are then mounted on a mandrel and dipped to seal the intermediate layer that contains the therapeutic agent (see col. 4 lines 47-52). Thus, Buirge teaches that the individual stents cut from the long rod are further processed for use as stents. Buirge does not teach or disclose detachable portions 154 that are removed from the permanent portion 158 and discarded and only the permanent portion 158 is used (see page 6 lines 8-12, 24-26).

Second, Buirge does not teach means for retaining the preliminary stent by an end of the detachable portion (see page 6 line 27 to page 7 line 14). At most, Buirge discloses forming a three layer long tube on a mandrel via a dip coating process. A process whereby each layer is formed by dipping the mandrel into a polymeric solution and after the formed stent pump is hardened and dried, the laminate structure is removed from the mandrel by pulling out the core rod and pulling on the shrink tubing (see col. 4 lines 32-52). The Examiner is incorrectly equating the mandrel disclosed by Buirge with the retainer claimed and described by the Applicant. The Applicant specifically provides that any method of retaining the preliminary stent that limits contact of the retainer to the detachable portion of the preliminary stent may be used (see page 7 lines 12-14). Buirge discloses that the mandrel comprises a core rod that is dipped, thus the core rod acts as a mold for the stent-pump. Therefore, by necessity, the core rod

must contact the entire stent pump during the forming procedure. Thus, for at least these reasons, the Buirge patent does not anticipate claim 17. Claims 19-20 depend from claim 17 and include all of the limitations of that claim. For at least this reason claims 19-20 are allowable over the Buirge patent.

Regarding claim 23, claim 23 recites a stent coating system that includes, among other elements, a retainer comprising a first retaining portion and a second retaining portion, the preliminary stent disposed between the first retaining portion and the second retaining portion. As stated above, the Buirge patent teaches a mandrel that comprises a core rod that is dipped in polymeric solution to form the stent pump. Thus, the Buirge patent does not teach a stent coating system wherein the preliminary stent is *disposed between* the first retaining portion and the second retaining portion (emphasis added). For at least this reason the Buirge patent does not anticipate claim 23.

Withdrawal of the rejection of claims 1-6, 17, 19-20 and 23 under 35 USC 102(b) is respectfully requested.

B. Claims 1, 3, 4, 6 and 21-22 were rejected under 35 U.S.C. 102(b) as being anticipated by Frantzen (US5782907).

The Examiner's rejection of claims 1, 3, 4, 6 and 21-22 under 35 U.S.C. 102(b) as being anticipated by the Frantzen patent is traversed. As noted above, claims 1, 3, 4, 6 and 21-22 have been cancelled by the current amendment. The withdrawal of the rejection of claims 1, 3, 4, 6 and 21-22 as being anticipated by Frantzen is respectfully requested.

35 U.S.C. §103 Rejections

To establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations. See, MPEP §2143.

A. Claims 7-16 were rejected under 35 U.S.C. 103(a) as being unpatentable over Buirge in view of admissions in the present specification

The Examiner's rejection of claims 7-16 under 35 U.S.C. 103(a) as being unpatentable over Buirge in view of admissions in the present specification is traversed because the Examiner has failed to establish a *prima facie* case of obviousness as required by MPEP §2143.

First, Buirge does not teach or suggest all of the claim limitations of independent claim 7. Claim 7 recites a method for producing a stent comprising providing a preliminary stent comprising a permanent portion and a detachable portion, the detachable portion comprising a first detachable portion and a second detachable portion; contacting an end of the detachable portion with at least one retainer; applying a coating to an outer surface of the preliminary stent; pooling a portion of the coating adjacent a contact point where the detachable portion contacts the retainer; and detaching the detachable portion with a pooled coating from the permanent portion.

As discussed above, Buirge merely teaches a method of forming a stent-pump upon a forming mandrel. Buirge does not teach a preliminary stent comprising a permanent portion and a detachable portion that comprises a first detachable portion and a second detachable portion as claimed and described by the Applicant. Additionally, Buirge does not teach contacting an end of the detachable portion with at least one retainer. Again, as discussed above, Buirge discloses a forming mandrel for use as a mold for forming the entire stent-pump. Buirge does not disclose a retainer that contact the ends of a preliminary stent.

Second, there is no teaching or suggestion within Buirge in view of the present specification to lead one of skill in the art to arrive at the invention as claimed. In fact, Buirge teaches away from the invention in teaching that the individual coated and cured stent pump is removed from the forming mandrel (Buirge col. 4, lines 43 – 57), without the need to remove the stent pump from a coated detachable portion with a pooled coating as required by the present claims.

Buirge also teaches away in that it discloses that rigid layer 16 provides structural integrity and acts as a stent (Buirge, col. 3, lines 39-41). As such, the dipping process to form the long tube with layers 12, 14 and 16 and then subsequently cutting the long tube, is the process of forming stent pumps to then be cut into individual stents for further processing, not the process of coating an individual stent as required by the present invention.

Additionally, Buirge does not teach or suggest, alone or in combination with the alleged admissions, coating an outer layer of the stent as required by claim 7. At most, Buirge teaches the coating of the ends of individual stent pumps after the stent pumps have been removed from

the forming mandrel, and cut into individual stents in order to seal the intermediate layer 14. For at least these reasons, the withdrawal of the rejection of claims 7-16 under 35 U.S.C. 103(a) is requested.

New Claims 24-30

New claims 24-30 are patentable over the cited art for at least the same reason as stated above for claims 17 and 23. Support for new claims 24-30 can be found at least on page 6 line 3 to page 7 line 27 and FIG. 2. No new matter has been added with this amendment.

Conclusion

For the foregoing reasons, Applicant believes all the pending claims are in condition for allowance and should be passed to issue. The Commissioner is hereby authorized to charge any additional fees which may be required under 37 C.F.R. 1.17, or credit any overpayment, to Deposit Account No. 01-2525. If the Examiner feels that a telephone conference would in any way expedite the prosecution of the application, please do not hesitate to call the undersigned at telephone (707) 543-5021.

Respectfully submitted,

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